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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,882	12/01/2000	William Lee	00786-429001 / MGH-1420.0	5708

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EXAMINER
FORTUNA, ANA M

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/728,882	Applicant(s) LEE ET AL.
	Examiner Ana M Fortuna	Art Unit 1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *22-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7/2/01* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 10-11, 12, 13-14, 18-19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Onishi et al (5,547,576)(hereinafter '576). Reference '576 discloses a process of removing virus from a liquid sample using a cationic (positively charged) membrane (column 3, lines 29-68 and column 4, lines 1-28, and 63-66). '576 discloses the membrane pore size as claimed in claims 1-2 (abstract, line 4, and column 4, lines 3-6). The step of passing the sample containing virus through the filter and removing 99.9 % or more of the virus is disclosed by the reference above, as claimed in claims 1 and 10-11 (column 14, lies 16-26). Regarding claims 1 and 3, making the membrane by graft copolymerization method, e.g. forming surface graft radicals by polyglycidyl acrylate or methacrylate on the surface of a hydrophobic membrane selected, from polypropylene, PVDF, etc, and further formation of the cationic membrane by reaction with ethyleneimine or polyethyleneimine to form a copolymer of polyethylaminated polyglycidyl (methacrylate) or acrylate is disclosed by '576 (column 6, last paragraph, column 7, lines 1-11, lines 48-68, column 8, lines 1-68, through column 9, lines 1-6). As to claim 12, at least one of the virus removed I s a retrovirus, e.g. HIV (column 16, lines 53-63, specifically line 61). As to claims 13-14, samples comprising

protein are disclosed in '576 (column 10, lines 35-37), the capability of removing less than 10 % of the protein in the sample seems to be inherent of the cationic filter, since the filter has the same membrane support material, porous size and the same groups attached to the support membrane, as discussed above. As to claim 20, bioactive viruses are disclosed (column 10, lines 28-34).

With regard to claims 18-19, eluting the virus with a saline solution, e.g. PBS buffer is disclosed in reference '576 (column 14, lines 22-26).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4-5, 6-9, 15-17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al (5,547,576)(hereinafter '576). The membrane components and properties and the process of using it in a virus removing process has been discussed in the paragraph above. Reference '576 does not discloses the side chains length as claimed in claims 4-5, however, teahes the compositions an/or reaction of components generating the side chains, e.g. polyglycidyl acrylate or methacrylate (used to introduce surface graft radicals) (column 8, lines 13-16, and 38-41). Further reaction with diethylamine is also disclosed (column 5, line 36-43, column 6, line58-64). It would have been obvious to one skilled in the art at the time the invention was made to produce side chains with the same chain average length when selecting

compositions capable of forming the same copolymer on the surface of the membrane support, as suggested in reference '576. In regard to claims 6-7, the amount o side chains engrafted or the degree of grafting is not detailed in reference '575 teaches providing a charge on the membrane surface within the range of 1 x 10(exp –4) eq/g or more, more preferably 4 x10(exp-4) eq/g or more (column 7, lines 35-38). It would have been obvious to one skilled in the art at the time the invention was made to control the drafting (engrafting), to provide a cationic level or charge on the membrane surface, or adjust the number of side chains (ethylamine compound) reacted with the radicals produced by the acrylate on the membrane surface, to produce a change capable of performing the virus removal function required, as disclosed in reference '576. As to claims 8-9, the degree of engrafting is not disclosed in terms of percentages in reference '576, however, it should have been expected by the skilled artisan for a membrane produced by the same method and the same composition.

As to claim 15, and 21, the plasma rate and degree of concentration is not disclosed, however, by providing more membrane surface area, or subjecting the sample to multiple filtration treatment with the cationic membrane of reference '576, higher flow rate and concentrations levels can be expected by one skilled in the art at the time the invention was made, based on the membrane composition, and pore size, and surface area available for filtration of the sample. As to claims 16-17, the flow rate for the specific samples treated is not specifically mentioned in reference '576. The membrane support , pore size and its water transmission rate are disclosed (column 9, lines 30-38), the sample flow is expected to be lower than that of the water, based on sample

density , by using a membrane provided with the same charge, form the same charged compounds, and having the same membrane support and pore size one skilled in the art at the time the invention was made can expect the same sample flow rate when subjected to the same pressure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (703) 308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Ana M Fortuna
Primary Examiner
Art Unit 1723

AMF
August 4, 2003